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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/369,992	08/06/1999	ANNA KATE URSULA KARA	64-99	7524

23713 7590 08/14/2002

GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/369,992

Applicant(s)

Kara et al

Examiner

Portner

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 6, 1999
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-45 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1-45 are pending.

#### ***Sequence Compliance***

1. The instant specification is now in sequence compliance.

#### ***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, drawn to a method of detecting Plasmodium malarial agent utilizing an LSU rRNA gene probe or primer, classified in class 435, subclass 6.
  - II. Claims 16-28, 30 and 31, drawn to a method of detecting Plasmodium falciparum or vivax or ovale or malariae utilizing an cox-l gene probe or primer, classified in class 435, subclass 6.
  - III. Claim 29, drawn to a method of detecting a specific species of Plasmodium based upon a combination of probes and primers for both LSU rRNA and cox-l genes, classified in class 435, subclass 6.
  - IV. Claims 32-34, composition kits of claim 40-41, 43-44 (in so far as claims 40-41 and 43-44 depend from claims 33-34), and claim 42, 45 (kit dependent from claim 34) drawn to probe and primer compositions that will hybridize to LSU rRNA, classified in class 536, subclass 23.1.

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V. Claims 35-37, 38, 39, composition kits of claim 40-41, 43-44 (in so far as claims 40-41 and 43-44 depend from claims 35-37, 38 ) drawn to probes and primer compositions for the cox-I gene, classified in class 536, subclass 24.33.

VI. Claims 40-45 composition kits (in so far as the claims recite a combination of probes or primers of claims 33-38 ) drawn to probes and primer compositions for both LSU rRNA and the cox-I gene, classified in class 536, subclass 23.7.

3. Inventions Group I or II and Group II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Groups I and II have separate utility such as detection reagents for LSU rRNA or mitochondrial coxI genes respectively. See MPEP § 806.05(d).

4. Inventions Groups IV or V or VI and Groups I, II or III, respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the nucleotide can be used in a method of making a polypeptide .

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and each sequence requires a different search based upon differences in the molecular structure, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I: Method of using:

- a. SEQ ID NO 1, nucleotides 1147-1740;
- b. SEQ ID NO 5;
- c. SEQ ID No 6;
- d. SEQ ID No 19; and
- e. SEQ ID No 20.

Group II: Method of using (cox-I gene probe, primer, primer pair or one or more primer pairs)

- |                     |                         |
|---------------------|-------------------------|
| i. SEQ ID NO 21;    | ix. SEQ ID No 17;       |
| ii. SEQ ID No 22;   | x. SEQ ID No 18;        |
| iii. SEQ ID No 11;  | xi. SEQ ID No 11 & 12;  |
| iv. SEQ ID No 12;   | xii. SEQ ID NO 13 & 14  |
| v. SEQ ID No 13;    | xiii. SEQ ID No 11 & 15 |
| vi. SEQ ID No 14;   | xiv. SEQ ID No 11 & 16  |
| vii. SEQ ID No 15;  | xv. SEQ ID No 11 & 17   |
| viii. SEQ ID No 16; | xvi. SEQ ID No 16 & 18  |

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Group III: Method of using:

Select one from each of section A & B: (an LSU rRNA reagent together with a cox-l reagent)

Section A

SEQ ID NO 1, nucleotides 1147-1740;

SEQ ID NO 5;

SEQ ID No 6;

SEQ ID No 19; and

SEQ ID No 20.

Section B

SEQ ID NO 21;

SEQ ID No 17;

SEQ ID No 22;

SEQ ID No 18;

SEQ ID No 11;

SEQ ID No 11 & 12;

SEQ ID No 12;

SEQ ID NO 13 & 14

SEQ ID No 13;

SEQ ID No 11 & 15

SEQ ID No 14;

SEQ ID No 11 & 16

SEQ ID No 15;

SEQ ID No 11 & 17

Group VI: compositions and kits, wherein the kits comprise a positive standard together with the composition.

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f. SEQ ID NO 1, nucleotides 1147-1740;

g. SEQ ID NO 5;

h. SEQ ID No 6;

i. SEQ ID No 19; and

j. SEQ ID No 20.

Group V: compositions and kits, wherein the kits comprise a positive standard together with the composition (cox-I gene probe, primer, primer pair or one or more primer pairs)

i. SEQ ID NO 21;

ix. SEQ ID No 17;

ii. SEQ ID No 22;

x. SEQ ID No 18;

iii. SEQ ID No 11;

xi. SEQ ID No 11 & 12;

iv. SEQ ID No 12;

xii. SEQ ID NO 13 & 14

v. SEQ ID No 13;

xiii. SEQ ID No 11 & 15

vi. SEQ ID No 14;

xiv. SEQ ID No 11 & 16

vii. SEQ ID No 15;

xv. SEQ ID No 11 & 17

viii. SEQ ID No 16;

xvi. SEQ ID No 16 & 18

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Group VI: compositions and kits, wherein the kits comprise a positive standard together with the composition.

Select one from each of section A & B: (an LSU rRNA reagent together with a cox-I reagent)

Section A

SEQ ID NO 1, nucleotides 1147-1740;

SEQ ID NO 5;

SEQ ID No 6;

SEQ ID No 19; and

SEQ ID No 20.

Section B

SEQ ID NO 21;                      SEQ ID No 17;

SEQ ID No 22;                      SEQ ID No 18;

SEQ ID No 11;                      SEQ ID No 11 & 12;

SEQ ID No 12;                      SEQ ID NO 13 & 14

SEQ ID No 13;                      SEQ ID No 11 &15

SEQ ID No 14;                      SEQ ID No 11 &16

SEQ ID No 15;                      SEQ ID No 11 &17



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7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-3, 5-11, 14-15 for Group I; Claims 16, 21-27 for Group II; are generic.
8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 12, 2002

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600